TCTR ID : TCTR20200604007

OTHER ID :

Overall Recruitment Status : Recruiting

Prospective registration
This protocol was registered before enrollment of the first participant.

Tracking Information

First Submitted Date : 02 June 2020

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Title

Public Title : The Physical Activity at Work (PAW) study: a cluster randomised trial of a multi-component short-break intervention to reduce sitting time and increase physical activity among office workers in Thailand

Acronym : No Data

Scientific Title : The Physical Activity at Work (PAW) study: a cluster randomised trial of a multi-component short-break intervention to reduce sitting time and increase physical activity among office workers in Thailand

Sponsor ID/ IRB ID/ EC ID : 62-01764

Registration Site : Thai Clinical Trials Registry

URL : https://www.thaiclinicaltrials.org/show/TCTR20200604007

Secondary ID : No Secondary ID

Ethics Review

1. Board Approval : Submitted, approved

Approval Number : 4/2563

Date of Approval : 22 July 2020

Board Name : Ethical Review Committee for Research in Human Subjects

Board Affiliation : Ministry of Public Health, Thailand

Board Contact : Business Phone : 6625906171 Ext. 2

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Business Address : ECMOPH, floor 3, building 2, Department of Medical Services, Ministry of Public Health, Nonthaburi, 11000

Sponsor

Source(s) of Monetary or Material Supports : Thai Health Promotion Foundation

Study Primary Sponsor : Thai Health Promotion Foundation

Responsible Party : Name/Official Title : Health Intervention and Technology Assessment Program

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Study Secondary Sponsor : Health Intervention and Technology Assessment Program

Protocol Synopsis

Protocol Synopsis : This study will investigate the effectiveness of a multi-component short break intervention on the reduction of SB during office hours.

Methods/Design: This two-armed Physical Activity at Work (PAW) cluster randomised controlled trial will recruit 360 office workers from 16 offices in the Thailand Ministry of Public Health. Offices will be randomised to either the intervention group or the control group. The multicomponent intervention is informed by the Social Ecological Model and Behaviour Change Techniques and contains four components: (i) organizational, including heads of the participating divisions leading exercises, sending encouragement text messages and giving rewards; (ii) social, including team movement breaks and group-related rewards; (iii) environmental, including posters to encourage exercise; and (iv) individual components including real-time PA feedback via an individual tracker. The main intervention component will be the short break intervention. The primary outcome of this study is the sedentary time of office workers. Secondary outcomes include time spent on PA, cardiometabolic outcomes, work productivity, musculoskeletal pain, self-report of comorbidities and quality of life scales. The study also includes process and economic evaluations from the individual and societal perspective.

Discussion: The study will be the first study in Thailand to investigate the effect of a short-break intervention at the workplace on SBs of office workers and health outcomes. The study will also include a cost-effectiveness analysis to inform investments on short break interventions in Thailand.Background

High levels of sedentary behaviour (SB) are associated with non-communicable diseases. In 2016, the estimated total healthcare expenditure from physical activity (PA) in Thailand added up to $190 million in international dollars. The challenge to reduce SB and increase PA among office workers is more urgent now than ever as Thailand is in the midst of transforming itself from a predominantly rural country to an increasingly urban one. This study will investigate the effectiveness of a multi-component short break intervention on the reduction of SB during office hours.

Method

Setting: The study will be located at the Department of Medical Services (DMS), Ministry of Public Health (MOPH) in Nonthaburi Province. Employees are working in central offices with fixed desks. Work tasks comprise mostly computer-based work, but also involve meetings and traveling to meet with officers from other ministries. The offices are all located in the same building on level 2 to 6.

Study Design and Randomization: This study is a clustered randomised controlled trial with two arms. We will include at least 16 offices (8 offices per arm) from the Department of Medical Services DMS, MOPH. Cluster randomisation by offices minimises the problem of cross-contamination between the intervention arms due to environmental changes in the offices. After baseline measurements, offices will be matched at a ratio of 1:1 based on the number of office workers in the offices. Each matched-pair will randomly allocate one office as intervention group and the other as control.

Data Collection

The duration of the research will be 18-months from the start of the intervention (6-months of intervention and 12-months follow-up, in addition to the baseline data collection), and participants will be requested to remain continuously enrolled during this period. Figure 1 provides an overview of the timeline of the PAW trial. Survey data will be collected at five time points: baseline, 6th month, 12th month and the 18th month after baseline assessment. Data will be collected by a trained research team, supervised by the core research team to ensure quality and consistency of the data collected. Survey will be interviewer administered. Invasive cardiometabolic measurements will be taken by trained physicians or nurses at baseline, 6th month, and 12th month. Demographic information will only be measured once at baseline. The main challenge will be to trigger sustained adherence to short breaks, and not just a short-term behaviour change. In that regard, implementing a follow-up period that is sufficiently long to assess these long-term effects is important. As a token of appreciation, all participants who have completed follow-up at 6th, 12th and 18th month will receive a small incentive of 500 THB (US $16) at 6th month, and 250 THB (US$ 8) each at 12th and 18th month. Participants will be compensated 1000 THB in total if they have participated till the end of the trial (US$ $32).

Commitment contract. A commitment contract is a binding agreement people â€œsign with themselvesâ€• to ensure that they will follow through with their intentions. [46] They usually offer people the opportunity to deposit money that they will receive back only if they fulfil their commitment. This is a way of leveraging loss aversion (people generally dislike losses more strongly than they enjoy equivalent gains) to strengthen self-control and drive sustained behaviour change. Self-funded commitment contracts have been successful at increasing exercise (47), smoking cessation (Gine et al., 2010) and weight loss [35]. Importantly, using them in conjunction with periodic incentives is a promising, cost-effective alternative to continuous incentives. [47]

Data Collection
Primary Outcomes: The primary outcome of this study is measured by minutes spent in SB. The accelerometer that will be used is the ActiGraphTM wGT3X-BT tri-axial accelerometer (ActiGraph, Pensacola, Florida, USA). Participants will be advised to wear the ActiGraph accelerometer on their waist, above the right hip, with an elastic belt during their waking hours, excluding time spent in water-based activities, for a period of 10 days [38]. The device will be initialized at a sample rate of 30 Hz. Participants will be taught how to wear the device and will receive an information booklet with the instructions for reference. ActiGraph is a tri-axial accelerometer that measures SB and physical activities by categorising count data into different categories. These categories are defined as sedentary (150 and below counts per minute), light activity (151 to 2689 counts per minute), moderate activity (2690 to 6167 counts per minute) and vigorous activity (6168 and above counts per minute) [39]. Participants will be asked to wear the trackers during waking hours. They will be given an option to put on the device when they sleep. Participants will be given activity logs to record the start and end date and time of wearing the tracker. When participants return the trackers, they will be asked to fill in a short questionnaire about activities they engaged in when they took off the ActiGraph e.g. duration and frequency of swimming, as participants are advised to take off the tracker for water-based activities. The activity log will be used together with daily data to assess adherence of wearing the ActiGraph trackers. To encourage adherence to wearing ActiGraph at night, participants will be given an additional 150 THB (US$ 5) per data collection. No incentive will be given if participants wear ActiGraph during sleep but not during the day. Participants will be able to receive

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an additional of 600 THB (US $20) in total if they participate in all data collection rounds, and wore ActiGraph both during the day and during sleep. Reminders to wear the trackers will be sent via the LINE messaging app.

Secondary Outcomes: Secondary outcomes will include the impact of the intervention on other PA such as, time spent in light activities, moderate to vigorous activities. The secondary PA outcomes will be measured using ActiGraphTM wGT3X-BT tri-axial accelerometer (ActiGraph, Pensacola, Florida, USA) and the General Physical Activity Questionnaire (GPAQ). Other secondary outcomes include the impact of the interventions on cardiometabolic outcomes. The cardiometabolic outcomes consist of the following physical measurements:
â€¢ waist circumference and neck circumference
â€¢ systolic blood pressure and diastolic blood pressure
â€¢ resting heart rate
â€¢ body weight
â€¢ height and body mass index (BMI).
Weight and height will be measured without shoes to the nearest 100 g and 0.1 cm, respectively. Body mass index (BMI) will be calculated by dividing weight in kilograms with the square of height in meters. Systolic and diastolic blood pressures will be measured after the participants had rested for at least 15 minutes with an automatic blood pressure monitoring by trained research assistants. Waist circumference (cm) will be measured at the middle point between the lowest rib and iliac crest in the standing position. Neck circumference (cm) will be measured with head positioned in Frankfurt horizontal plane using non-stretchable plastic tape to the nearest 1mm. It will be measured at the level just below the laryngeal prominence perpendicular to the long axis of the neck.

We will also be collecting blood biomarkers outcomes:
â€¢ fasting plasma glucose (HbA1c)
â€¢ fasting insulin
â€¢ homeostasis model assessment of insulin resistance (HOMA-IR)
â€¢ serum uric acid
â€¢ lipid profile
â€¢ high sensitivity C-reactive protein (hs-CRP).

Further Secondary Outcomes: QALYs will be obtained from three surveys for cost-effective evaluation. One is the EuroQol-5 Dimension (EQ-5D). Participants will be able to rate the severity of their disease on the EuroQol-5 Dimension (EQ-5D) [40]. The instrument encompasses five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Participants will be asked to rate their health state on three levels of severity. QALYs will also be taken from work productivity, which will be assessed using the Work Productivity and Activity Impairment Questionnaire (WPAI) and musculoskeletal health which will be assessed using the Standardised Nordic Questionnaire [41]. In addition, the study will ask participants for demographic information and self-report of comorbidities.

Measurement Timeline of Outcomes The primary outcome will be measured at baseline, 6th month, 12th month and 18th month follow-up. The non-invasive cardiometabolic outcomes will be measured at baseline and every three months until the 12th month and then again at the 18th month. The invasive cardiometabolic outcomes will only be measured at baseline, 6th month and the 12th month. The tertiary outcomes such as the EQ-5D, musculoskeletal health, WPAI and self-report comorbidities will be measured together with the non-invasive cardiometabolic measures at baseline, 3rd, 6th, 12th and the 18th month (Table 1). The economic impact will be evaluated at 6th month and at the end of the trial follow-up period.
Sample Size Eligible office workers from the DMS will be invited to participate in the trial. To detect a difference in the primary outcome of 23.3 minutes in sedentary time from prior randomised trial [22], the sample size was calculated with a standard deviation (SD) of 45.5, based on a two-tailed significance level of 5% and power of 80%. The calculation assumes a conservative intra-class correlation coefficient of 0.05 and a coefficient of variation of 0.60 to account for varying cluster sizes in the study. There are 16 clusters (offices), each cluster varying between 7 to 62 office workers. Assuming an average cluster size of 22 participants, we will yield a design effect of 2.44. Therefore, the sample size required to detect a difference of 23.3 minutes in SB is 293 participants. To conform to best practice, this sample size will be inflated by 20% to account for drop-outs and potential loss of participants due to non-compliance to primary outcome or chances of faulty devices. Hence, a sample size of 360 participants is needed.

Data analyses

Primary and Secondary Outcomes: The primary aim of this study is to investigate the impact of introducing short movement breaks during office hours on SB of office workers both during and outside working hours. This primary analysis will be conducted using multilevel linear mixed-effect model with time spent in SB as the dependent variable and the intervention allocation as the independent variable. The model will be adjusted for confounders such as baseline SB, baseline characteristics (such as age and gender) and device wear times when necessary. The model will adjust for clustering by individuals, offices and matching as random effects. The random effects will assume an unstructured variance-covariance matrix structure estimated by the restricted maximum likelihood.

In our primary analysis mentioned above, we will adopt the complete case analysis approach where missing

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values will not be replaced. Secondary outcomes relating to physical activities and productivity will be analysed using similar methodology. These analyses will be conducted at 6-month and 12-month follow-up to investigate the effectiveness of the intervention as well as the sedentary behavioural changes post-intervention. Sensitivity analysis using the intention-to-treat approach where missing data will be imputed will also be carried out for the primary outcome of our study. Baseline characteristics of participants who are lost to follow up or dropped out of the study will be compared to those who completed the study to investigate differential dropout between intervention and control groups.

Economic Evaluation: The economic evaluation aims to report two pieces of cost-effectiveness information of the PAW program: 1) short-term economic impact, and 2) long-term economic impact. The analysis will be conducted from the perspective of public health care payer. The costing data will be collected from the trial. For the longer-term costs, e.g. treatment costs for stroke and diabetes, will be retrieved from domestic literature or relevant cost database [42].

First, we aim to conduct a person-level economic evaluation to report a short-term impact of the PAW program using the data from the trial within the study period. Based on data from the trial, we will compare the costs and outcomes of the intervention against control using the net benefit regression framework [38] from the public health care payerâ€™s perspective. Costs will include costs incurred to the Ministry of Health in Thailand including intervention costs and costs of treating related health problems (e.g., musculoskeletal diseases, diabetes and hypertension). The effectiveness outcomes for this analysis will include: 1) absolute working hours; 2) absenteeism and presenteeism; 3) key clinical indicators e.g. cardiovascular disease (CVD) risk scores and 4) QALYs. Separate analyses will be conducted for each outcome. The output of this analysis will be expressed as an incremental net benefit of PAW compared to no PAW. We will also estimate incremental cost-effectiveness ratios (ICERs) over the study period, for example, incremental cost of the PAW program (compared to no PAW) to obtain one more absolute working hour, and incremental cost for one more QALYs gained. The use of regression will allow us to adjust for potential confounders and to calculate the clustered standard errors using the sandwich variance estimators of Huber and White [39] to account for a clustered randomised design in which the outcomes of interest may be correlated. Uncertainty of the cost-effectiveness findings within the study timeframe will be characterised using a cost-effectiveness acceptability curve and a 95% confidence interval [40]. Moreover, additional subgroup analyses (e.g., by sex and age groups) could be explored.

Furthermore, we aim to construct a hybrid model, with a decision tree and Markov models also using the public health care payerâ€™s perspective. Model-based economic evaluations will help to assess the economic impact and benefits of PAW implemented at the workplace in the long term. Decision tree model (Figure 3) compares the current situation where PAW has not been implemented and the alternative policy option of PAW. The outcome of each choice will be whether or not a change in CVD risk scores (based on Rama-EGAT heart score) [43, 44] after exposing to the interventions. Next, Markov model will be performed to predict lifetime costs and outcomes that occurred after the change in CVD risk scores. The Markov model, which will run separately using transitional probabilities, follows the natural history of coronary heart disease (CHD), stroke, and diabetes based on the CVD risk scores. The Markov model will be run using the lifetime time horizon with a cycle length of one year. All costs and outcomes occurring after one year were discounted at a rate of 3%, as recommended by iDSI Reference Case [45]. Inputs to the models will be obtained from the trial and literature review. The outputs from cost-effectiveness analysis will be presented as cost, QALYs, and ICER to reflect a value for money of PAW. Sensitivity analyses including univariate and probabilistic sensitivity analysis will be performed to describe the uncertainty of the findings.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied :	non communicable diseases
Keywords :	non communicable disease

Eligibility

Inclusion Criteria :	1) have an end date for employment after the study completion date 2) are legally able to consent, i.e. age 18 years and above 3) do not have a disability on the upper or lower body that limits their mobility 4) have a permanent office workstation within one of the clusters included in the trial 5) have at least 3 working days per week before the start of the trial 6) owns and uses a smartphone compatible with the Fitbit application 7) are willing to be randomised into one of the two study interventions
Gender :	Both
Age Limit :	Minimum : 18 Years Maximum : 0 N/A (No limit)
Exclusion Criteria :	1) For candidates with non-communicable diseases (NCDs) (e.g. diabetes) or metabolic risk factors (e.g. hypertension, hyperlipidemia), additional data on the history of disease and medication dosage will be collected to assess whether they are safe to participate in the trial. 2) Office workers will be excluded from the study if one is away on an extended leave or a personal retreat

for more than two weeks or is pregnant

Accept Healthy Volunteers : Yes

Status

Overall Recruitment Status : Recruiting

Key Trial Dates	Study Start Date (First enrollment) : 07 August 2020	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 26 February 2021	Indicate Type : Anticipated
	Study Completion Date : 25 February 2022	Indicate Type : Anticipated

Design

Study Type : Interventional

Primary Purpose : Prevention

Study Phase : N/A

Intervention Model : Parallel

Number of Arms : 2

Masking : Single Blind

Allocation : Randomized

Control : Active

Study Endpoint Classification : Efficacy Study

Sample size

Planned sample size : 360

Intervantion Arm 1

Intervention name : multi-component short-break intervention

Intervention Type : Active Comparator

Intervention Classification : Behavioral

Intervention Description : Intervention Package: The PAW intervention development was guided by the Social-Ecological Model which highlights that behaviours are shaped by various factors on different levels. Individual Components Information Booklet: Both the control and intervention groups will receive an information booklet about the benefits and consequences of PA and â€œ7 easy exercises to an active lifestyleâ€• for the office environment. The booklet will also include instructions on how to use the activity tracker (ActiGraph and Fitbit for the intervention group). For the intervention group the booklet will also include information about the intervention components that are relevant to them, e.g. eligibility criteria for winning rewards. Fitbit: The intervention group will be given a Fitbit tracker (Inspire HR) to track their PA throughout the trial. The proper use of the trackers will be explained and self-help program booklet (which is handed out prior to this meeting). Fitbit is an activity tracker that provides real time feedback and allows self-monitoring of steps as well as calories burned, distance covered, active minutes, heart rate, time asleep each day and proportion of hourly activity completed amongst others. It provides feedback through a smartphone app via Bluetooth connection. The device also sets haptic vibration feedback for hourly activity during office hours (9am to 6pm) to nudge participants to walk at least 250 steps each hour. Participants will be encouraged to wear the device as frequent as possible to obtain the most accurate results. Physical Components Posters: The intervention group will also be exposed to posters of exercises and stretching in their offices to encourage participants to be physically active. Posters will also include information about the health consequences of SB and PA information about the study (e.g. rewards) (Appendix Figures 1a-c). Cultural Components Short Breaks: The social intervention consists of team movement breaks, with each cluster forming a team. Groups can choose to take four movement breaks of 3-5 minutes each at 9.30am, 10.30am, 2.30pm and 3.30pm, within a 30 minutes time window. An exercise or dance video with music will be played and participants are encouraged to dance/exercise along with the video. An alarm will signal that it is time for a movement break. If participants work from home, they will be encouraged to join take the breaks together online through a video conferencing software such as Zoom. Organisational Components Leadership Support: Leaders within DMS will encourage participants to take part in the study via Line and Facebook, offering rewards and recognition to participants who do well. Line is a freeware app for instant communications on electronic devices such as smartphones, tablet computers, and personal computers that is used by 44 million residents in Thailand or 63% of the Thai population. Participants will be told that they will receive this recognition in advance. Consequently, participants will receive the recognition and reward from the leader if they are eligible for a reward in a given week. Financial Incentive Component: Members in the intervention group are eligible to participate in the lottery if the individual completed at least 60% of the short breaks (i.e. at least 12 breaks of 3-5 mins in length in the week), with a minimum of 100 steps during each exercise session. One winner each week will receive a financial incentive of 500 THB (US$ 16). The adherence to the movement breaks will be measured weekly using the Fitbit activity trackers.

Intervantion Arm 2

Intervention name : controlled arm

Intervention Type : Active Comparator

Intervention Classification : No treatment

Intervention Description : Health education: physical activity and sedentary fact sheets

Outcome

Primary Outcome

1. Outcome Name : impact of introducing short movement breaks during office hours on SB of office workers both during

Metric / Method of measurement : multilevel linear mixed-effect model with time spent in SB as the dependent variable and the interve

Time point : 6 months and 15 months after the start of interventions

Secondary Outcome

1. Outcome Name : time spent on physical activity

Metric / Method of measurement : AciGraph accelerometer

Time point : baseline, 6 months, and 15 months after the start of interventions

2. Outcome Name : musculoskeletal pain

Metric / Method of measurement : Standardised Nordic Questionnaire questionnaire

Time point : baseline, 6 months, and 15 months after the start of interventions

3. Outcome Name : cardiometabolic outcomes

Metric / Method of measurement : physical examination and Blood collection for lab biomarkers

Time point : basesline, 6 months and 15 months after the start of interventions

4. Outcome Name : work productivity

Metric / Method of measurement : Work Productivity and Activity Impairment Questionnaire questionnaire

Time point : baseline, 6 months, and 15 months after the start of interventions

5. Outcome Name : QALYs

Metric / Method of measurement : EuroQol-5 Dimension (EQ-5D) questionnaire

Time point : baseline, 6 months, and 15 months after the start of interventions

Location

Section A : Central Contact

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Section B Facility Information and Contact

1. Site Name : Department of Medical services, Ministry of Public Health

	City : Nonthaburi	State/Province : Nonthaburi	Postal Code : 11000
	Country : Thailand	Recruitment Status : Completed	
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Investigator Name	First Name : Katika	Middle Name :	Last Name : Akksilp
	Degree : MD	Role : Principal Investigator	

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Organization Affiliation : Health Intervention and Technology Assessment Program

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : No Data
Plan description : No Data

Publication from this study

MEDLINE Identifier : No Data
URL link to full text publication : No Data

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